



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15UX]

[Docket No. CDC-2015-0011]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites

comment on "Continuing and New International and US Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response". Under the current 60-day Federal Register Notice, the CDC is announcing its intention to seek three-year OMB approval to continue several Ebola-related information collections beyond their current emergency expiration dates and to conduct newly proposed information collections within international borders of Ebola-affected West African countries and within the domestic borders of State, Territorial and Local (STL) public health authorities in the US. These existing "source" information collections and new information collection requests (ICRs) will be submitted under four "destination" ICRs for Office of Management and Budget (OMB) approval.

DATES: Written comments must be received on or before

[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0011, by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.

- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](https://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](https://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Continuing and New International and US Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The international outbreak of Ebola virus disease (EVD) in West Africa began March 10, 2014. The initial cases were from southern Guinea, near its rural border with Liberia and Sierra Leone. Highly mobile populations contributed to increasing waves of person-to-person transmission of EVD that occurred in multiple countries in West Africa. The Centers for Disease Control and Prevention (CDC) Emergency Operations Center (EOC) was activated on July 9, 2014, to help coordinate technical assistance and control activities with international partners and to deploy teams of public health experts to the affected countries.

The operations turned to the United States (US) when the first imported case of EVD was diagnosed in Texas on September 30, 2014. In response, on October 11, 2014, the CDC Quarantine Stations and the Department of Homeland Security (DHS) Customs and Border Patrol (CBP) mobilized to screen, detect, and refer arriving travelers who were potential persons at risk for EVD to appropriate state, territorial, and local (STL) authorities. The CDC also increased its commitment to support STL public health authorities to combat and control the spread of EVD within

their jurisdictions.

Thus in 2014, the CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in West Africa, at US ports of entry, and within STL jurisdictions. These procedures allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness, and death from the uncontrolled spread of EVD.

With this notice, the CDC is announcing its intention to seek three-year OMB clearances to continue several Ebola-related information collections beyond their current emergency expiration dates and to conduct newly proposed information collections within international borders of Ebola-affected West African countries and within the domestic borders of STL public health authorities in the US. These existing "source" information collections and new ICRs will be submitted under four "destination" ICRs for OMB approval.

On the international front, CDC seeks to continue to address key public health surveillance and medical treatment objectives in collaboration with West African

ministries of health (MoHs), the World Health Organization (WHO), and other key partners. Examples of "source" information collections include: (1) "2014 Emergency Response to Ebola in West Africa" (OMB Control No. 0920-1033, expiration date 4/30/2015) which helped to establish country EVD surveillance systems for case investigations and contact tracing; and (2) the emergency clearance for "Household Transmission Survey - a Public Health Response Evaluation in Western Area, Sierra Leone" (OMB Control No. 0920-1043, expiration date 07/31/2015). This was a one-time investigation that will be the first of a new "destination" generic clearance ICR that will identify ways to improve established surveillance systems in other West African countries and settings.

On the domestic front, CDC's information collections will focus on continued support of STL public health authorities and healthcare providers in EVD infection control and notifiable disease reporting to the CDC. CDC wishes to extend OMB clearance for the "source" emergency information collection, "Ebola Virus Disease in the United States: CDC Support for Case and Contact Investigation" (OMB Control Number 0920-1045, expiration date: 07/31/2015). For this, the CDC proposes a new "destination"

ICR titled "National Disease Surveillance Program III - CDC Support for Case Investigations, Contact Tracing, and Case Reports." This new mechanism will be designed to allow CDC to conduct active disease surveillance in support of and at the request of STL authorities among respondents that may include the general public, workers, and STL authorities.

The CDC will seek OMB approval for another new domestic ICR titled "CDC Emergency Operations Center Clinical Inquiries" an Ebola-related information collection currently in use without an OMB control number. Early in the response, a call center was quickly set up to support urgent inquiries about active monitoring, diagnosis, and clinical treatment of EVD. The clinical inquirers were STL authorities and health facilities that were notified by US Quarantine Stations that persons requiring investigation and possible treatment for EVD were arriving in their respective jurisdictions and facilities.

Although initiated by EOC Task Forces, the lead CDC center for the emergency response (based on subject matter, mission, and program areas) will sponsor these information collections. These information collections will align with their legislative authority, which is Section 301 of the

Public Health Service Act (42 U.S.C. 241).

There are no costs to the respondents other than their time. The total annualized burden requested is 378,695 hours.

Estimated Annualized Burden Hours

A - "CDC International Emergency Response Case and Contact Surveillance Systems"

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
General Public	A1 - Viral Hemorrhagic Fever Case Investigation Form (English)	13,650	1	20/60	4,550
General Public	A2 - Viral Hemorrhagic Fever Case Investigation Form (French)	7,350	1	20/60	2,450
General Public	A3 - Viral Hemorrhagic Fever Case Investigation Short	5,850	1	10/60	975

	Form (English)				
General Public	A4 - Viral Hemorrhag ic Fever Case Investiga tion Short Form (French)	3,150	1	10/60	525
General Public	A5 - Viral Hemorrhag ic Fever Contact Listing Form (English)	19,500	1	15/60	4,875
General Public	A6 - Viral Hemorrhag ic Fever Contact Listing Form (French)	10,500	1	15/60	2,625
General Public	A7 - Viral Hemorrhag ic Fever Contact Tracing Follow-Up Form (English)	195,000	1	63/60	204,750
General Public	A8 - Viral Hemorrhag ic Fever Contact Tracing Follow-Up Form (French)	105,000	1	63/60	110,250
General	A9 -	195,000	1	5/60	16,250

Public	Ebola Virus Disease Case Contact Questionn aire (English)				
General Public	A10 - Ebola Virus Disease Case Contact Questionn aire (French)	105,000	1	5/60	8,750
General Public	A11 Ebola Outbreak Response Sexual Transmiss ion Adult Case Investiga tion Form (English)	500	1	30/60	250
General Public	A12 Ebola Outbreak Response Sexual Transmiss ion Adult Case Investiga tion Form (French)	300	1	30/60	150
Healthcare Workers or Proxy	A13 - Healthcar e Worker Ebola Virus Disease Exposure Report - West Africa	1,950	1	30/60	975

	(CDC-WHO) (English)				
Healthcare Workers or Proxy	A14 - Healthcar e Worker Ebola Virus Disease Exposure Report - West Africa (CDC-WHO) (French)	1,050	1	30/60	525
Healthcare Workers or Proxy	A15 - Healthcar e Worker Ebola Virus Investiga tion Questionn aire (Liberia)	400	1	30/60	200
Healthcare Workers or Proxy	A16 - Healthcar e Worker Ebola Virus Disease Exposure Report (Sierra Leone)	400	1	30/60	200
Healthcare Workers or Proxy	A17 - Health Facility Assessmen t and Case Finding Survey (English)	3,900	1	30/60	1,950
Healthcare Workers or Proxy	A18 - Health Facility Assessmen	2,100	1	30/60	1,050

	t and Case Finding Survey (French)				
Total					361,300

B - Generic Clearance for "Household Transmission Surveys
in West Africa: Public Health Response Evaluations"

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Case-patients or caregiver (as proxy)	B1 - Initial Questionnaire for Case-Patients - SAMPLE FORM	357	1	20/60	119
Heads of household	B2 - Questionnaire for Ebola-affected Households - SAMPLE FORM	357	1	20/60	119
Household contacts of case-patient	B3 - Questionnaire for Investigation of Household Contacts of Ebola-infected Case-patients - SAMPLE FORM	3,570	1	30/60	1,785

Household contacts of case-patient	B4 - Contact Exit Questionnaire - SAMPLE FORM	3,570	1	5/60	298
Laboratory analyst and project staff	B5 - Patient Laboratory Record - SAMPLE FORM	573	1	5/60	48
Total					2,369

C - "National Disease Surveillance Program III - CDC Support for Case Investigation, Contact Tracing, and Case Reports"

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
General Public - Case	C1 - Ebola Virus Disease Case Investigation Form - United States	15	1	30/60	8
General Public - Case	C2 - Symptom Monitoring Form	15	57	5/60	72
General Public - Person Under Investigation (PUI)	C3 - Ebola Virus Disease Person Under Investigation (PUI)	300	1	10/60	50

	Form				
General Public - Person Under Investigation (PUI)	C2 - Symptom Monitoring Form	300	42	5/60	1,050
General Public - Contact	C4 - Ebola Virus Disease Contact Tracing Form - United States	105	1	10/60	18
General Public - Contact	C2 - Symptom Monitoring Form	105	42	5/60	368
Healthcare Workers	C5 - Ebola Virus Disease Tracking Form for Healthcare Workers with Direct Patient Contact	600	15	10/60	1,500
Healthcare Workers	C2 - Symptom Monitoring Form	600	57	5/60	2,850
Laboratory Personnel	C6 - Ebola Tracking Form for Laboratory Personnel	600	15	10/60	1,500
Laboratory Personnel	C2 - Symptom Monitoring Form	600	57	5/60	2,850

Environment al Services Personnel	C7 - Ebola Tracking Form for Environme ntal Services Personnel	600	15	10/60	1,500
Environment al Services Personnel	C2 - Symptom Monitorin g Form	600	57	5/60	2,850
State, Territorial , and Local Public Health Authorities and Their Delegates	C8 - Daily and Weekly Report	15	42	10/60	105
Total					14,721

D - "CDC Emergency Operations Center Clinical Inquiries"

Type of Respondents	Form Name	No. of Responden ts	No. of Responses per Responden t	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
State and Local Health Departments	D1 - Clinical Inquiries Database	420	1	15/60	105
Clinicians and Other Providers	D1 - Clinical Inquiries Database	800	1	15/60	200
Total					305

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director

Centers for Disease Control and Prevention
[FR Doc. 2015-07037 Filed: 3/26/2015 08:45 am; Publication Date:
3/27/2015]